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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/403,625	02/07/00	DEBYSER	W VANM131.001A

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EXAMINER

FRONDA, C

ART UNIT	PAPER NUMBER
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1652

DATE MAILED:

11/06/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/403,625

Applicant(s)
Debyser et al.

Examiner
Christian L. Fronda

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above, claim(s) 1-5 and 14-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

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DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group V, claims 6-13, in the **RESPONSE TO RESTRICTION REQUIREMENT AND PRELIMINARY AMENDMENT** dated September 28, 2001 (Paper No. 8) is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicant's election with traverse of the species of SEQ ID NO: 1 in Paper No. 8 is acknowledged. The traversal is on the grounds that the claimed xylanase inhibitor contains both SEQ ID NO: 1 and SEQ ID NO: 2 and that both amino acid sequences should be examined together.

Upon further consideration SEQ ID NO: 1 and SEQ ID NO: 2 will both be examined. The requirement is still deemed proper and is therefore made FINAL.

Claims 1-5 and 14-47 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

2. Claims 6-13 and amino acid sequences SEQ ID NO: 1 and SEQ ID NO: 2 are under consideration in this Office Action.

Claim Rejections - 35 U.S.C. § 101

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 6-13 are rejected under 35 U.S.C. 101 because the claims are directed toward non-statutory subject matter.

In the absence of the hand of man, naturally occurring proteins and/or nucleic acids are considered non-statutory subject matter. *Diamond v. Chakrabarty*, 206 USPQ 193 (1980). This rejection may be overcome by amending the claims to contain wording such as "An isolated and purified proteinic or glycoprotein inhibitor of xylanase".

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Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 6-13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to (1) any proteinic or glycoprotein xylanase inhibitor having any structure or amino acid sequence and (2) any xylanase inhibitor comprising any amino acid sequence that is at least 70% or 85% identical to SEQ ID NO: 1 or SEQ ID NO: 2. The specification, however, only provides a single representative species encompassed by these claims: an isolated and purified proteinic xylanase inhibitor comprising SEQ ID NO: 1 and SEQ ID NO: 2. There is no disclosure of any particular structure to function/activity relationship in the single disclosed species. The specification also fails to describe additional representative species of these polynucleotides by any identifying structural characteristics or properties other than inhibiting xylanase for which no predictability of structure is apparent. Given this lack of additional representative species as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention. Claims 7-13 which depend from claim 6 are also rejected because they do not correct the defect of claim 6.

7. Claims 6-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated and purified proteinic xylanase inhibitor comprising SEQ ID NO: 1 and SEQ ID NO: 2, does not reasonably provide enablement for (1) any proteinic or glycoprotein xylanase inhibitor having any structure or amino acid sequence, (2) any proteinic or glycoprotein xylanase inhibitor comprising any amino acid sequence that is at least 70% or 85% identical to SEQ ID NO: 1 or SEQ ID NO: 2, or (3) any proteinic or glycoprotein xylanase inhibitor comprising the amino acid sequence of SEQ ID NO: 1 or SEQ ID NO: 2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in *re Wands* [858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988)]. The *Wands* factors

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are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The nature and breadth of the claims encompass (1) any proteinic or glycoprotein xylanase inhibitor having any structure or amino acid sequence, (2) any proteinic or glycoprotein xylanase inhibitor comprising any amino acid sequence that is at least 70% or 85% identical to SEQ ID NO: 1 or SEQ ID NO: 2, or (3) any proteinic or glycoprotein xylanase inhibitor comprising the amino acid sequence of SEQ ID NO: 1 or SEQ ID NO: 2. The specification provides guidance and examples for making an isolated and purified proteinic xylanase inhibitor comprising SEQ ID NO: 1 and SEQ ID NO: 2. While molecular biological techniques and genetic manipulation techniques are known in the prior art and the skill of the artisan are well developed, knowledge regarding the specific biological source of any proteinic or glycoprotein xylanase inhibitor having any structure or amino acid sequence, any proteinic or glycoprotein xylanase inhibitor comprising any amino acid sequence that is at least 70% or 85% identical to SEQ ID NO: 1 or SEQ ID NO: 2, or any proteinic or glycoprotein xylanase inhibitor comprising the amino acid sequence of SEQ ID NO: 1 or SEQ ID NO: 2 is lacking. Furthermore, knowledge regarding the specific amino acid sequence of any proteinic or glycoprotein xylanase inhibitor comprising only SEQ ID NO: 1 or SEQ ID NO: 2, or the amino acid residues to substitute, delete, insert, or combinations thereof in SEQ ID NO: 1 or SEQ ID NO: 2 to make a protein or glycoprotein which is still able to inhibit xylanase enzyme activity and comprises an amino acid sequence that is at least 70% or 85% identical to SEQ ID NO: 1 or SEQ ID NO: 2 is lacking. Thus, searching for the biological source of the claimed proteinic or glycoprotein xylanase inhibitor and the specific amino acid residues to change in SEQ ID NO: 1 or SEQ ID NO: 2 to make a protein or glycoprotein which is still able to inhibit xylanase enzyme activity is well outside the realm of routine experimentation and predictability in the art of success is extremely low.

The amount of experimentation to determine the biological source of the claimed proteinic or glycoprotein xylanase inhibitor or the specific amino acid residues to change in SEQ ID NO: 1 or SEQ ID NO: 2 to make a protein or glycoprotein which is still able to inhibit xylanase enzyme activity is enormous. Such experimentation entails searching for an organism out of a vast number of organisms which contains proteinic or glycoprotein xylanase inhibitor or inserting, deleting, substituting, or combinations thereof amino acid residues in SEQ ID NO: 1 or SEQ ID NO: 2 and determining whether the protein or glycoprotein is still able to inhibit xylanase enzyme activity and has an amino acid sequence that is at least 70% or 85% identical to SEQ ID NO: 1 or SEQ ID NO: 2. Since routine experimentation does not include screening vast numbers of organisms for a specific organism which contains proteinic or glycoprotein xylanase inhibitor or inserting, deleting, or substituting amino acids in SEQ ID NO: 1 or SEQ ID

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NO: 2 and screening for proteins which still inhibit xylanase activity and comprises an amino acid sequence that is at least 70% or 85% identical to SEQ ID NO: 1 or SEQ ID NO: 2, where the expectation of obtaining a desired organism containing the claimed xylanase inhibitor and the specific amino acid residues to change in SEQ ID NO: 1 or SEQ ID NO: 2 is unpredictable, the Examiner finds that one skilled in the art would require additional guidance, such as information regarding the specific organism which contains the claimed xylanase inhibitor or the specific amino acid residues to change in SEQ ID NO: 1 or SEQ ID NO: 2 to make a protein which is still able to inhibit xylanase activity and comprises an amino acid sequence that is at least 70% or 85% identical to SEQ ID NO: 1 or SEQ ID NO: 2. Without such a guidance, the experimentation left to those skilled in the art is undue. Claims 7-13 which depend from claim 6 are also rejected because they do not correct the defect of claim 6.

Conclusion

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (703)305-1252. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703)308-3804. The fax phone number for this Group is (703)308-0294. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703)308-0196.

CLF



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